II. REMARKS

Upon entry of the amendment, claims 1 to 15, 19 to 30, 33 to 37 and 40 to 51 will be pending. A marked-up version showing the amendments to the specification and the claims is attached hereto as Exhibit A.

A. Regarding the Amendments

The specification has been amended to replace Applicant's Attorney Docket No. with U.S. Serial No. 09/801,393, which had not yet been assigned at the time the subject application was filed. As such, the amendment merely addresses a formality, and does not add new matter.

Claims 1, 9, 23, 37 and 40 have been amended to indicate that a composition of the invention and a composition useful in practicing a method of the invention is one "consisting essentially of" a β-cyclodextrin. The amendment is supported, for example, at page 5, lines 6-13, and lines 21-23; and page 23, lines 1-26, which discloses a composition can contain β-cyclodextrin is active in preventing transmission of a sexually transmitted pathogen. As such, the amendments do not add new matter.

Claims 3, 20 and 34 have been amended to correct a typographical error. As such, the amendments do not add new matter.

Claim 4 has been amended to insert the term "virus", which inadvertently was omitted. The amendment is supported, for example, by the language of claim 2, which provides antecedent basis of claim 4, and, therefore, does not add new matter.

Claims 13, 14, 28 and 29 have been amended to more fully recite formulations of the invention. The amendments are supported, for example, at page 26, line 1, to page 27, line 24; and page 28, lines 14-24. As such, the amendments do not add new matter.

New claims 46 to 51 have been added. New claims 46 and 47 are supported, for example, at page 26, line 1, to page 27, line 24; and page 28, lines 14-24. New claims 48 to 51

are supported, for example, at page 28, line 25, to page 29, line 2. As such, the newly added claims do not add new matter.

B. Regarding the Priority

It is stated in the Office Action that the subject application has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119. The specification has been amended to insert the Serial No. of the priority application, which had not yet been assigned at the time the subject application was filed. In view of the amendment, it is submitted that the requirements for obtaining the benefit of priority have been met.

C. Claim Objections

It is stated in the Office Action that the term "herpesvirus" is misspelled in claims 3, 20 and 34. The claims have been amended to substitute the term "herpes virus". As such, it is respectfully requested that this objection to the claims be withdrawn.

D. Rejection under 35 U.S.C. § 112

The rejection of claim 39 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed.

Claim 39 inadvertently referred back to "claim 27" rather than correctly referring to "claim 37", which provided antecedent basis. In view of the amendment to claim 37, however, claim 39 has been cancelled. As such, it is submitted that the rejection is moot.

E. Prior Art Rejections

The various rejections of claims 1 to 8, 9 to 22, 23 to 36, 37 to 39, and 40 to 45 under 35 U.S.C. § 103(a) as allegedly obvious over Bergeron et al. (U.S. Pat. No. 6,068,851) are respectfully traversed.

The claims are variously rejected based on Bergeron et al. describing, for example, compositions and methods for preventing the transmission of sexually transmitted pathogens through mucosae and/or skin (column 3, lines 14-21; column 7, lines 9-50), wherein the composition can act as a physical chemical or pharmacological barrier (column 3, lines 34-67), and particularly on their describing encapsulation of HIV protease and reverse transcriptase inhibitors in cyclodextrin (column 4, lines 1-14). It is stated in the Office Action that, while Bergeron et al. do not describe 2-hydroxypropyl-βCD, it would have been obvious to use such a βCD because it is "widely used in the pharmaceutical industry to solubilize and stabilize active agents" (Office Action, page 5; emphasis added). In view of the amendments to the claims, the various grounds of rejection, each of which is based on the Bergeron et al. reference, are addressed together.

The claims are directed to compositions "consisting essentially of" a β-cyclodextrin (βCD), and to methods of using such compositions to prevent a sexually transmitted disease. It is well recognized that use of the transitional phrase "consisting essentially of" in the claim limits the scope of the claim to the specified materials and those that do not materially affect the basic and novel characteristics (see MPEP § 2111.03). As disclosed in the specification, the basic and novel characteristic of the claimed invention is the disclosure that a βCD can be used alone as a pharmaceutical agent to prevent the transmission of a sexually transmitted disease (see, for example, page 5, lines 6-13; page 25, lines 1-7).

Prior to Applicant's disclosure, cyclodextrins, including βCDs, were used only as solubilizing agents or as carriers of pharmaceutically active compositions (see, for example, specification at page 5, lines 15-21). However, it was not known that βCDs, alone, have a pharmaceutical activity or, in particular, that a βCD can be used to reduce the risk of infection or transmission of a sexually transmitted disease. In this respect, Applicant points out that Bergeron et al. refer to the use of "cyclodextrins" only as an encapsulating agent for "inhibitors" such as HIV protease and reverse transcriptase inhibitors (see column 3, line 67, to column 4, line 11;

see, also, Office Action, as cited above). Thus, Bergeron et al. refer to the previously known use of a cyclodextrin as a delivery vehicle, but do not teach or suggest a composition consisting essentially of a βCD as the active agent, or the use of such a composition for reducing the risk of infection or transmission of a sexually transmitted pathogen.

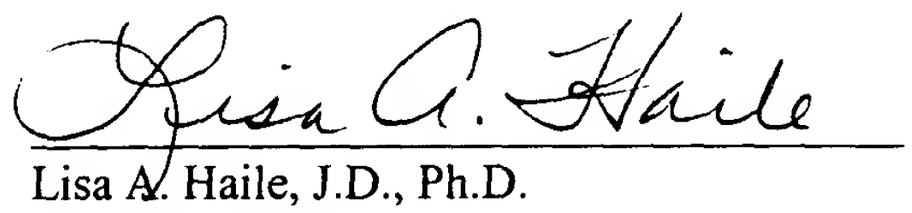
It is submitted that, prior to Applicant's disclosure, one of ordinary skill in the art would not have known or had any motivation to prepare a pharmaceutical composition consisting essentially of a βCD (claim 37) because it was not known that βCDs had a pharmaceutical activity, or that a composition for reducing the risk of transmission of a sexually transmitted disease consisting essentially of a βCD (claim 40) would be effective because it was not known that a βCD could, itself, be an active agent and reduce such a risk. Furthermore, it would not have been known nor would one have had reason to use a composition consisting essentially of a βCD to reduce the risk of infection (claim 9) or of transmission (claims 1 and 23) of a sexually transmitted pathogen or sexually transmitted disease. Accordingly, it is submitted that the claimed invention would not have been obvious in view of Bergeron al. and, therefore, is respectfully requested that the rejection of the claims be removed.

In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect respectfully is requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: July 12, 2002



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Enclosure: Exhibit A

EXHIBIT A

MARKED VERSION OF TITLE AND CLAIMS SHOWING THE AMENDMENTS

A. In the Specification

The paragraph at page 1, lines 4-8, was amended as follows (note: deletion of "underlining" that preceded Attorney Docket No. in application as originally filed):

This application is a continuation-in-part of U.S. Serial No. 09/801,393 [___ (Atty. Docket No. JHU1710-2)], filed March 7, 2001, which claims the benefit of priority under 35 U.S.C. § 119 of U.S. Serial No. 60/267,199, filed February 7, 2001; and U.S. Serial No. 60/187,784, filed March 8, 2000, the entire contents of each of which is incorporated herein by reference.

B. In the Claims

The claims were amended as follows:

1. (Amended) A method of reducing the risk of transmission of a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen with a composition consisting essentially of a β-cyclodextrin.

3. (Amended) The method of claim 2, wherein the enveloped virus is an immunodeficiency virus, a T lymphotrophic virus, a [herpesvirus] herpes virus, a measles virus, or an influenza virus.

4. (Amended) The method of claim 2, wherein the enveloped virus is a human immunodeficiency virus.

9. (Amended) A method of reducing the risk of a subject becoming infected with a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen in the subject with a pharmaceutical composition [comprising] consisting essentially of a β-cyclodextrin, thereby reducing the risk of the subject becoming infected with the sexually transmitted pathogen.

13. (Amended) The method of claim 8, wherein the pharmaceutical composition is formulated in a solution, a gel, a foam, an ointment, a cream, a paste, a lubricant, a jelly, or a spray.

14. (Amended) The method of claim 9, wherein the pharmaceutical composition is formulated in a suppository, a film, a vaginal disk, a bioadhesive polymer, a sponge, a diaphragm, a glove, a tampon, a pellet, a tablet, or a condom.

20. (Amended) The method of claim 19, wherein the enveloped virus is an immunodeficiency virus, a T lymphotrophic virus, a [herpesvirus] herpes virus, a measles virus, or an influenza virus.

23. (Amended) A method of reducing the risk of transmission of a sexually transmitted disease by a subject infected with a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen with a pharmaceutical composition [comprising] consisting essentially of a β-cyclodextrin, thereby reducing the risk of transmission of the sexually transmitted disease by the subject.

28. (Amended) The method of claim 23, wherein the pharmaceutical composition is formulated in a solution, a gel, a foam, an ointment, a cream, a paste, a lubricant, a jelly, or a spray.

29. (Amended) The method of claim 23, wherein the pharmaceutical composition is formulated in a suppository, a bioadhesive polymer, a vaginal disk, a film, a diaphragm, a glove, a tampon, a pellet, a tablet, or a condom.

34. (Amended) The method of claim 33, wherein the enveloped virus is an immunodeficiency virus, a T lymphotrophic virus, a [herpesvirus] herpes virus, a measles virus, or an influenza virus.

37. (Amended) A pharmaceutical composition, [comprising] consisting essentially of a β-cyclodextrin[and an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof].

40. (Amended) A composition for reducing the risk of transmission of a sexually transmitted disease, the composition [comprising] consisting essentially of a solid substrate and a β-cyclodextrin.